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Tennessee Board of Pharmacy News

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Board of Pharmacy Executive Director Reports Annual Registrations

The Tennessee Board of Pharmacy Executive Director Reginald "Reggie" Dilliard, DPh, shares the following information regarding current Board registrations as of January 1, 2021. (Numbers in parentheses denote an increase/decrease from last year):

- **Pharmacists: 13,220 (+373)**
- **Pharmacies: 2,924 (-15)**
- **Manufacturer/wholesaler/distributor: 2,654 (+87)**
  - ◊ Includes third-party logistics providers
  - ◊ Includes virtual manufacturers and virtual wholesalers
- **Researchers (Including drug detection dog handlers): 294 (+2)**
- **Technicians: 18,913 (-334)**
  - ◊ **Technicians in the last three years: (-958)***
- **Pharmacy interns: still pending (rules being promulgated).**

*Dr Dilliard noted the alarming decrease in pharmacy technicians over the last three years.

Board Office Staff Delivers the Take-Home Message

Board staff reminds registrants of the following regulations:

Board Rule 1140-03-.01(1): Face-to-Face Counseling – Waiver Expired

Investigators have observed pharmacists neglecting to verbally counsel patients on new prescriptions and pharmacy staff neglecting to verbally offer the pharmacist's counsel on refills. Remember that even a Drug Enforcement Administration (DEA) Schedule II stimulant, opioid, or other type of prescription that may have been written the same way for months or years is still considered a new prescription, which requires the pharmacist to perform face-to-face counseling unless the patient refuses the counsel. If the patient refuses counsel, the refusal must be made to the pharmacist face to face, or it will be in violation of the Board rule.

Board Rule 1140-14-.12(2)(a): Stocking of ADMs in Long-Term Care Sites – Waiver Expired

The waiver that allowed stocking of medications in the automated dispensing system to be performed without the direct supervision of a pharmacist has expired. Therefore, all stocking of medications in the automated dispensing system shall be completed by a pharmacist, pharmacy intern, or pharmacy technician under the direct supervision of a pharmacist unless a specific waiver for an individual pharmacy has been granted from presentation to the Board.

Pharmacies Are Found to Have Early Refill Policies in Place

Be Aware of the 'Refill Too Soon'

(Reprinted and updated in part from the Board's March 2010 *Newsletter.*)

Refer to Rule 1140-03-.03. According to paragraph (6),

> No pharmacist, or pharmacy intern or pharmacy technician under the supervision of a pharmacist, shall compound or dispense any medical or prescription order except upon the following conditions: (a) All medical and prescription orders shall be compounded and dispensed **in strict conformity** with any directions of the prescriber. (emphasis added)

In (d) of this rule, it is also written that "if a prescription contains a statement that during any particular time it may be refilled at will, **the order shall be refilled in strict conformity to dosage directions."** (emphasis added) The exception is that it may not be refilled after the expiration of the time specified or one year from the date the order was originally issued or dispensed, whichever comes first. The six-month expiration would apply to Schedule III and IV (and Schedule V, depending on DEA interpretation) for controlled substance (CS) refills. In a case presented to the Board, a complainant alleged that respondent pharmacists contributed to his CS addiction. Pharmacy records reported that the complainant's medications were refilled early each

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

Guidelines, Materials Available to Health Care Providers for Safely Administering COVID-19 Vaccines

Guidelines and materials are available to support health care providers with safely administering the coronavirus disease 2019 (COVID-19) vaccine, including safe practice recommendations from the Institute for Safe Medication Practices (ISMP) and a United States Pharmacopeia (USP) toolkit.

After numerous reports of errors or hazards associated with the administration of COVID-19 vaccines, ISMP is sharing safe practice recommendations.

A new USP toolkit is also available to facilitate operational efficiencies that can help accelerate delivery and support safe handling of COVID-19 vaccines while maintaining quality and ultimately the public's trust. Download the USP toolkit.

FDA Issues Guidance to Protect Consumers From Methanol Poisoning

Food and Drug Administration (FDA) has issued guidance for industry, *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19).* The guidance is intended to help pharmaceutical manufacturers and pharmacists who engage in drug compounding to avoid using pharmaceutical alcohol contaminated with or substituted with methanol in drug products. FDA noted that methanol is not an acceptable ingredient for any drug product and should not be used. The guidance is available on the FDA website.

Standardize Concentrations for Oral Liquid Preparations

ISMP Institute for Safe Medication Practices An ECRI Affiliate

This column was prepared by ISMP, an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert! newsletters at* www.ismp.org.

Few would disagree that standardizing the concentrations of drugs has enormous potential for increasing safety, especially in pediatric care. Standardization limits the risk of variation, especially when patients are transitioned from hospital to home or have prescriptions filled at different pharmacies. However, ISMP has learned of multiple instances in which unrecognized differences or changes in drug concentrations led to confusion and dosing errors.

In one example, a patient was prescribed hydroxyurea, an antineoplastic agent. The community pharmacy compounded a 50 mg/mL suspension for the patient with instructions to take 13 mL (650 mg) for each dose. When the patient was later admitted to the hospital, the inpatient pharmacy prepared their standard concentration of 100 mg/mL, but the same dose volume of 13 mL was ordered. As a result, the patient received doses of 1,300 mg for several days before the error was recognized. It is unclear why the community pharmacy prepared a 50 mg/mL concentration. Perhaps the prescriber ordered that concentration or that was the concentration with which the pharmacist was most familiar.

Similar concentration mix-ups have been reported in literature. In one case, the oral class 1c antiarrhythmic medication flecainide was involved. The parents of a nine-month-old infant were told to increase the child's dose volume of flecainide to 4 mL, assuming the concentration was 5 mg/mL as in the original prescription.[1] However, the parents refilled the prescription at a different pharmacy and received the drug in a 20 mg/mL concentration. The patient received 80 mg/4 mL, a fourfold overdose, resulting in wide complex tachycardia and QRS prolongation.

There have been efforts, including those by a collaborative led by the University of Michigan[2]and the American Society of Health-System Pharmacists (ASHP)[3], to publish lists of consensuses and literature-based standard concentrations. In fact, for the medications involved in the cases above, both the University of Michigan and ASHP standard recommendations are in alignment – hydroxyurea 100 mg/mL and flecainide 20 mg/mL. However, the outreach and communication of these standardization efforts do not appear to be reaching prescribers and pharmacists. Both inpatient and outpatient practitioners need to get on the same set of standard concentrations for compounded oral liquids. It is imperative that both medical and pharmacy professional organizations develop and implement effective strategies to reach and influence practitioners to use the published standard concentrations. ISMP urges prescribers and pharmacists to review the University of Michigan and

ASHP lists and consider adopting the proposed standard concentrations. Your efforts can help reduce the risk of medication errors.

It is also important for pharmacists to provide patients or caregivers with appropriately sized metric-only dosing devices (eg, oral syringes) to measure and administer doses. Label directions for patients and caregivers should include the dose in terms of mL (not teaspoonfuls), matching the dosing device. The community pharmacy label should also include the concentration next to the drug name. To be sure patients or caregivers are able to use the dosing device and measure the proper dose, use the teach-back method to demonstrate how to measure and administer prescribed amounts. This also gives pharmacists, patients, and caregivers an opportunity to catch an error.

References

1. Wang GS, Tham E, Maes J, et al. Flecainide toxicity in a pediatric patient due to differences in pharmacy compounding. Int J Cardiol. 2012;161(3):178-9.
2. *www.mipedscompounds.org/*
3. *www.ashp.org/-/media/assets/pharmacy-practice/s4s/docs/Compound-Oral-Liquid.ashx*

Opioid Use Disorder Educational Programs, Resources Available for Pharmacists

Through its Opioid Use Disorder (OUD) Education Program, the College of Psychiatric and Neurologic Pharmacists (CPNP) provides educational programs and resources that can help pharmacists during the ongoing opioid epidemic. These educational opportunities include Accreditation Council for Pharmacy Education-approved, on-demand programs covering subjects such as pharmacotherapy for OUD, comorbid disorders, and chronic pain and OUD. Toolkits and guides are available to assist pharmacists in the areas of intervention, medication management, and naloxone access.

These educational materials and resources can be accessed through the CPNP website.

National Diabetes Prevention Program – How Pharmacists Can Get Involved

Pharmacists can play a key role in preventing type 2 diabetes by helping to expand the reach of the National Diabetes Prevention Program (National DPP) – a program led by the Centers for Disease Control and Prevention (CDC) that makes it easier for patients with prediabetes or who are at risk for type 2 diabetes to participate in evidence-based lifestyle changing programs to reduce their risk and improve overall health. CDC offers an action guide for community pharmacists that outlines ways pharmacies can raise awareness of prediabetes. The National DPP is a partnership among private and public organizations to screen and test for prediabetes and refer people with prediabetes to a CDC-recognized lifestyle change program participating in the National DPP, and deliver the National DPP lifestyle change program. More information about how pharmacists can participate is available on the CDC website.

Surgery Patients Receive More Opioids in the US Than in Other Countries

Patients in the US are prescribed a disproportionally higher number of opioids after surgeries compared to surgery patients in other countries, according to a new study. The study, published in the *Journal of the American College of Surgeons,* reviewed data from 2,024 surgery patients and found that 83% of US patients without pain were prescribed opioids, compared with 8.7% of non-US patients without pain. The authors concluded that US patients are prescribed more amounts of opioids at higher rates regardless of the severeness of their post-surgical pain. The authors recommend that more efforts are made toward ensuring that opioid prescriptions are tailored to patients' needs.

The full text of the study can be accessed by visting *www.journalacs.org/article/S1072-7515(20)32336-X/fulltext.*

Study Finds 94% Drop in Symptomatic COVID-19 Cases With Pfizer's Vaccine

A study by Israel's largest health care provider, health maintenance organization Clalit, reported that there is a 94% drop in symptomatic COVID-19 cases with the Pfizer vaccine. The study represents 600,000 people who received two doses of the Pfizer COVID-19 vaccine in Israel. Clalit, which covers more than half of all Israelis, noted the same group who received the COVID-19 vaccine doses was also 92% less likely to develop serious illness from the virus. The study compared the vaccine recipient group to another group of the same size and medical history who had not received the vaccines. Read the full study here.

NABP Executive Director/Secretary Addresses Pharmacists' Involvement in COVID-19 Vaccination During FIP Webinar

NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, presented during the International Pharmaceutical Federation's (FIP's) Regulators' Forum on pharmacists' involvement with COVID-19 vaccination on February 4, 2021. The webinar addressed a new regulatory vaccination preparedness self-assessment tool and risk assessment, the expanded roles for pharmacists, and data FIP has collected on vaccinations by pharmacists. View the webinar here.

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month. The recommendation of the Board was to authorize a formal hearing and levy a $500 fine to each pharmacist on duty.

Q. How do you make the decision to allow or decline an early refill?

A. If you fill a 30-day supply of a CS medication one day early each month, you have dispensed 12 extra days of medication for the year, and three days early each month would equal 36 days' worth. These amounts would **not** be considered filling the prescription in strict conformity with any directions from the prescriber. Historically, the Board has demonstrated that it understands the difference between extraordinary circumstances to fill early (eg, out-of-town travel, pharmacy closure on day refill is due) versus a trend in early refills.

Sterile Compounding Corner

Board of Pharmacy investigators have noted the following violations found in recent inspections.

Using hand sanitizer/hand scrub on top of sterile gloves: Hand sanitizer is generally not sterile and should only be used as indicated in United States Pharmacopeia Chapter <797>, directly **before** donning sterile gloves. It is permissible to use the hand sanitizer on the first set of gloves if another set is donned due to a hand allergy. However, it is better practice to find a different sanitizer if possible.

Moving hands in and out of the PEC without sanitizing with sterile alcohol: Remember that **every time** hands come out of the primary engineering control (PEC) to throw trash away, or to grab another component (eg, syringe, drug vial, IV bag), hands are to be resanitized. This action may require a great deal of sanitizing. Therefore, the registrant may wish to use a sanitized bucket or bin to transport sanitized products into the PEC at one time to decrease the in/out movements. It was once taught to remove all trash frequently. However, provided that the trash pile does not impede airflow, it is permitted to stay in the PEC and be removed later. Registrants should contact their local investigator for more information, if needed. (In/out is also mentioned in Food and Drug Administration (FDA) Insanitary Conditions Guidance.)

Line #47.03 of the Universal Inspection Form as part of the National Association of Boards of Pharmacy® Multistate Pharmacy Inspection Blueprint Program states the following: "Temperature monitoring is also performed in drug storage areas (if separate from the compounding areas). Temperature is maintained at controlled room temperature of 20°-25°C (68°-77°F) or as specified by FDA approved labeling for drug product storage." Specifically, does every room that holds an automated dispensing machine (ADM) need to have a designated monitor?

All medications must be kept within the designated manufacturer temperature limit or the pharmacy will be in violation of Board rule, Tennessee statute, and FDA regulation, causing for adulterated drugs. That being said, use your professional judgment. If the pharmacy only keeps compounded sterile products (CSPs) in the refrigerator, that should already be monitored. If the room where the ADM is located keeps the same temperature as the rest of the rooms on the floor where temperature is tracked, it is a judgment call. Does it feel warm when entering the room? A simple additional manual gauge will help determine if the limits of room temperature are being pushed. Ultimately, it is the responsibility of the designated person to make sure CSPs and components are kept at the proper temperature so that the beyond-use date (BUD) is not compromised.

Sterile water for cleaning purposes found opened and used up to the manufacturer's expiration date: No preservative or BUD documentation is noted as to how long the product will remain aseptic for use as a cleaning agent. If no documentation is available, then this component reverts to a six-hour BUD once opened.

Tennessee Pharmacy Recovery Network

If you need help with addiction or know an associate (pharmacist or pharmacy technician) who does, please contact Dr Baeteena Black, Tennessee Pharmacy Recovery Network (TPRN) program director, by phone at 615/256-3023 or by email at bblack@tnpharm.org. More information, including the reporting form, is located on the TPRN website.

Disciplinary Actions

For disciplinary actions taken against registrants licensed with the health-related boards, click here.

DEA Offers Online Reference for Code of Federal Regulations

According to James Stevens, supervisory diversion investigator for the DEA Nashville, TN office, the electronic version of Title 21, Code of Federal Regulations (CFR), Part 1300 et al is now available online. "It is updated frequently and is used by DEA to update the CFR on this website," said Stevens. He explained that it will be the most up-to-date version available.

Report Theft or Significant Loss

Per Title 21, CFR, Section 1301.76(b), registrants must notify their local DEA office, in writing, of the theft or significant loss of CS within one business day of discovery. Tennessee registrants may now satisfy this requirement by submitting all relevant information via email to tntheftorloss@usdoj.gov. Registrants must still complete DEA Form 106 and may do so online via the DEA website. You shall also satisfy the Board regulation to immediately report theft or loss and may do so by sending a copy to Dr Terry Grinder at terry.grinder@tn.gov.

Board Meeting Schedule

The Board extends an open invitation for all registrants and the general public to attend its public meetings at 665 Mainstream Drive, Nashville, TN 37243. The meetings are currently scheduled to begin at 9 AM. It is advised to check for schedule changes on the Board website under the Meeting Schedule tab.

The **2021** meeting schedule is as follows:

- July 13-14
- September 14-15
- November 16-17

Tennessee Board of Pharmacy Members

- Dr Katy Wright – President
- Dr Adam Rodgers – Vice President
- Dr Melissa McCall – Board Member
- Dr Richard Breeden – Board Member
- Dr Shanea Mckinney – Board Member
- Dr Rissa Pryse – Board Member
- Mr Jake Bynum – Public Member

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